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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,473	11/20/2003	Yoshiya Gunji	US-104	5759

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CERMAK & KENEALY LLP
ACS LLC
515 EAST BRADDOCK ROAD
SUITE B
ALEXANDRIA, VA 22314

EXAMINER

ROBINSON, HOPE A

ART UNIT	PAPER NUMBER
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1656

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/716,473	Applicant(s) GUNJI ET AL.	
	Examiner Hope A. Robinson	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) 5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/21/04; 4/6/04; 6/19/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

1. Applicant's election with traverse of Group I (claims 1-4 and 6) on October 19, 2005 is acknowledged. Claim 5 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.
2. The traversal is on the grounds that Groups I-II should be rejoined as the method and product search would not result in undue search burden. This argument is not persuasive as the invention consists of two different methods; no product claims are presently filed. Further, According to MPEP chapter 800, a restriction requirement is proper if the invention can be shown to be independent or distinct. The Office action mailed on September 23, 2005 established that the methods had acquired a separate status in the art thus not coextensive in search, thus poses a search burden. Applicant's arguments are not persuasive, and as the restriction requirement is proper based on the disclosure in the MPEP, the restriction requirement is final.

Information Disclosure Statement

3. The Information Disclosure Statements filed on December 21, 2004, April 6, 2004 and June 9, 2005 have been received and entered. The references cited on the

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PTO-1449 Form have been considered by the examiner and a copy is attached to the instant Office action.

Drawing

4. The drawings filed on November 20, 2003 have been accepted by the examiner.

Specification

5. The specification is objected to because of the following informalities:

- (a) The specification is objected to because the improper spacing of the words and the font used makes reading difficult. See for example, page 10, "Amethanol-utilizing bacterium" or "sequence ofSEQ ID NO:14", on page 13 and throughout the instant specification.

- (b) The specification is objected to as the priority information is not recorded on page 1 of the specification, for example, "This application claims benefit under 35 U.S.C. 119(a-d) to Application Number 2002-336346, filed November 20, 2002 in Japan.

Correction is required.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-4 and 6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification lacks complete deposit information for the strain of the invention. On pages 29 of the instant specification it is disclosed that the *E. coli* JM109 strain is transformed into plasmids which are deposited at the National Institute of Advanced Industrial Science and Technology, International Patent Organism Depository on June 4, 2001, for which no address is provided. It is stated that the deposits were made under the Budapest Treaty, however, no statements indicating that all restrictions on the availability to the public of these deposits will be irrevocably removed upon issuance of a patent is provided. Therefore, it is not known whether the information is publicly available or can be reproducibly isolated. Without publicly available deposit information one of skill in the art could not be assured of the ability to practice the invention as claimed.

Applicant's referral to the deposit on page 29 of the specification is noted but is considered insufficient assurance that all of the conditions of 37 CFR 1.801-1.809 have been met. If deposits have not been made under the Budapest Treaty, then in order to certify that the deposits meet the criteria set forth in 37 CFR 1.801-1.809, applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(A) During the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(B) All restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(C) The deposits will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(D) The deposits were viable at the time of deposit;

(E) The deposits will be replaced if they should ever become non-viable.

This requirement is necessary when a deposit is made under the provisions of the Budapest Treaty as the Treaty leaves these specific matters to the discretion of each member State. Amendment of the specification to disclose the date of the deposit and the complete name and address of the depository is required. For further information concerning deposit practice, applicants attention is directed to In re Lundak 773 F 2d 1216 227 USPQ CAFC and 37 CFR 1.801-1.809.

Absent adequate written description of the claimed invention a skilled artisan is being invited to perform undue experimentation. Therefore, for all these reasons the

specification lacks adequate written description, and one of skill in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

7. Claim 1-4 and 6 are rejected under 35 U.S.C. 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and the dependent claims hereto are indefinite for the recitation of "enhanced" as the claim does not set forth how much of an "enhancement is achieved". It is noted that claim 3 recites a more measurable standard for measuring the enhancement, however, claim 3 does not recite how much increase is seen in the copy number. See also claim 6, which recites the same language.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

8. Claims 1-2, 4 and 6 are rejected under 35 U.S.C. 102(a) as being anticipated by Ajinomoto Co., Inc. (EP 188 822, March 20, 2002), cited on the IDS.

Ajinomoto Co., Inc. teach an L-amino acid producing bacteria and a process for producing L-amino acid by culturing a *Methylophilus* bacterium which can grow by using methanol, resulting in enhancement of activity of several enzymes. The limitation of Entner-Doudoroff pathway is an inherent property of a methanol utilizing bacterium, thus anticipated. Further, the reference teaches the production of L-lysine, L-valine, -L-isoleucine etc. Therefore, the limitations of the claims are met by the reference.

Conclusion

9. No claims are presently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr, can be reached at (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS

Patent Examiner

Hope Robinson, MS

Patent Examiner

HOPE ROBINSON
PATENT EXAMINER

1/9/06